EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, Plaintiff, v. GLEN MULREADY, in his official capacity as Insurance Commissioner of Oklahoma, and the OKLAHOMA INSURANCE DEPARTMENT, Defendants.	)	Civil Action No. CIV-19-977-J

DECLARATION OF KIM A. CALDWELL

I, Kim A. Caldwell, am over 18 years of age and hereby declare as follows:

1. I am a registered pharmacist and I have been practicing pharmacy continuously for over 40 years. I have worked in a variety of settings, including key roles within small chain pharmacies, large chain pharmacies, and owning and operating an independent pharmacy. I have also worked for pharmacy benefit managers (PBMs) and other entities engaged in helping consumers have affordable access to prescription drugs. I make this declaration based upon my personal knowledge, except where stated to be on information and belief, and with respect to any such statements, I believe them to be true. If called upon to testify, I could competently testify to such facts.

Summary of Opinions

2. The Patients Right to Pharmacy Choice Act (the Act) harms PBMs in two principal ways. First, the Act will require PBMs to fundamentally restructure their business models. Second, the Act will cause PBMs to incur significant administrative costs. I will discuss the specifics of these harms further below.

3. PBMs use preferred pharmacy networks as a tool to provide cost-effective prescription drug coverage to health plans and their members. Preferred pharmacy networks contain prescription drug costs by incentivizing members to purchase their prescription drugs at pharmacies that agree to accept lower reimbursements. Pharmacies agree to these lower reimbursements in exchange for dispensing a higher volume of prescriptions. Preferred pharmacy networks are a central service that PBMs offer their customers.

4. The Act undermines the use of preferred pharmacy networks, because it prevents PBMs from limiting the number of pharmacies in their preferred pharmacy networks. As a result, PBMs will be unable to offer certain pharmacies increased business volume in exchange for lower prices and acceptance of higher quality standards. The likely result will be higher prices and lower service quality for plan beneficiaries. PBMs will therefore be unable to provide health plans with core elements of their business model.

5. In addition to contracting with pharmacy networks on behalf of health plans, PBMs provide a number of other services to health plans. PBMs process claims and reimbursements for prescription drugs that are covered under the plan. PBMs must

process these claims according to the terms of the health plan. PBMs also implement quality of care initiatives intended to improve health outcomes and to ensure that plan members have safe access to their prescription drugs.

6. The Act includes several provisions related to the processing and payment of claims. These provisions will prevent PBMs from processing claims according to the terms of the plan. For example, the Act requires a PBM to pay a pharmacy for a particular drug, on a unit-by-unit basis, no less than it pays a pharmacy affiliated with the PBM. In the event the affiliated pharmacy is reimbursed at a higher price for a particular drug, the PBM will not be able to reimburse the unaffiliated pharmacy at the contracted rate under the plan. This creates an administrative burden for multi-state plans, who will no longer be able to reimburse prescriptions according to the same terms regardless of where the prescription is filled. PBMs will have to create a separate mechanism for processing claims in Oklahoma than they have for the other 49 states.

7. The Act and its regulations will also impede a PBM's quality of care initiatives. First, by preventing PBMs from removing a pharmacy with a suspended pharmacist from their network, the Act limits a PBM's ability to ensure pharmacies in a plan's network meet the quality standards needed to ensure safe access to care. Second, PBMs often direct plan members with complex, chronic, or rare diseases to specialty pharmacies that specialize in providing complete disease management services that improve health outcomes. By applying the restrictions on limited pharmacy networks to

specialty pharmacies, the regulations prevent PBMs from ensuring that plan members with serious health conditions access the enhanced care they need.

8. The burden of administering the Act will be particularly acute during the COVID-19 pandemic. In my experience, the same staff at the PBM charged with implementing the PBM's COVID-19 response will also typically be responsible for implementing the Act. Implementing the Act will strain PBM resources at time when PBMs are aggressively working to ensure plan members have continued access to prescription drugs during a public health crisis.

Qualifications

9. My education and experience have prepared me to speak as an expert on the PBM industry and network pharmacy agreements. My complete CV is attached hereto as Attachment 1, and relevant experience is detailed below.

Education/Early Experience as Pharmacist

10. In 1974, I earned a Bachelor of Science in Pharmacy from Southwestern Oklahoma State University.

11. Following graduation, an externship, internship, and full licensure, I began my work as a registered pharmacist in East Texas in 1975. My first job was working for a small chain pharmacy, Drug Sav Company, which was based in Tyler, Texas. I subsequently worked for larger chain pharmacies, Skillerns and Sons (owned by Zale Corporation) and OSCO Drugs (owned by Jewel Corporation) while living in Longview Texas. I also briefly worked for the Texas Department of Human Resources.

12. In 1979, I purchased a small independent pharmacy in Athens, Texas, a community approximately 70 miles southeast of Dallas. At the time, Athens had a population of approximately 10,000 people. I owned and operated the independent pharmacy until 1985. At the same time, I served as a pharmacy consultant for various small, regionally located nursing facilities on weekends and other days off.

13. I sold the pharmacy in 1985. This business decision was precipitated by a series of events tied to financial conditions in the country from the late 1970s through the early 1980s. The county hospital near the pharmacy was sold to a larger, corporate operated hospital group, which built a new facility several miles away. Although the population had not grown, the number of pharmacies in the area had doubled. As a result, I understand the operational challenges and finances of independent pharmacies.

14. I also have significant experience in the practice and business of providing pharmacy benefits and care for larger populations. In retail pharmacy, the target is roughly 2000 patients per pharmacist. For managed care and PBMs, membership populations are often in the millions of lives. In 1991, I began to build professional skills that would allow me to provide services and benefits to larger populations. My first exposure to serving large populations was during a short-term assignment working for Kaiser/Foundation Health Plans of Texas. In the following years, I worked as a pharmacy manager for retail pharmacies including for an independent pharmacy, Anderson's Drug and a pharmacy department inside of a Brookshire's grocery store, both in Athens, Texas. In 1994, I became the Retail Pharmacy Manager at Baylor-Richardson Medical Center. In

that role, I established, managed, and operated a retail pharmacy within a medical office building attached to the parent hospital. In each of these roles, I was heavily involved in third-party relationships, contracts, terms, and audits. As part of my agreement to establish that outpatient retail pharmacy, I was allowed to begin pharmacy consultant services for a standalone, hospital owned clinic for geriatric patients.

Experience at PBMs

15. Based upon the work that I had implemented for the senior population in the geriatric clinic, in 1996, I was hired by the Dallas-Fort Worth branch of a large regional health plan, NYLCare of Texas, a multi-regional health plan owned by New York Life. While at NYLCare, among other duties, I worked closely with our network PBM on all contracted expectations and performances and managed our network pharmacy relationships. I also served on the Pharmacy and Therapeutics (P&T) Committee. I worked with pharmaceutical manufacturers, and built formulary offerings. Additionally, I often met with the key clients and their members. Following NYLCare, I became the PBM Pharmacy Director for Prudential Health Plan in North Texas.

16. In 1998, I began working for Advance Paradigm, a small PBM that later acquired PCS, Inc. to form AdvancePCS, where I served as Vice President of Pharmacy Regulations and Vice President of Clinical Operations. In these roles, I worked to enhance our PBM's clinical offerings and delivery of services. I helped to restructure AdvancePCS's mail order pharmacy quality controls and operational strategy. I also

served on the P&T Committee and worked on formulary development. Additionally, I worked closely with our pharmacy network team.

17. Most recently, I spent over ten years from 2008 through 2018 at Humana, Inc. (Humana), specifically within the Humana Pharmacy Solutions PBM division. Humana Pharmacy Solutions is a member of the Pharmaceutical Care Management Association (PCMA) and one of the largest PBMs in the country. At Humana, I built and led two teams: one focused entirely on pharmacy policy, and the other focused on targeted data and information. My duties crossed all areas of PBM functions and responsibilities. I advised on key components of Humana's operations including the P&T Committee, benefit design, pharmacy networks, and Part D plan bids.

18. I retired from Humana in July 2018. Since retiring, I have been engaged by a variety of entities to do consulting work on pharmaceutical health benefits and coverage, Medicare Part D, pharmacy policy, pharmacy operations, and PBMs, as well as data development and new financing models for future orphan/ultra-orphan therapies. I have previously consulted for PCMA.

Other Relevant Experience

19. In October 1997, I was appointed to the Texas State Board of Pharmacy. The Board of Pharmacy is a consumer protection agency of the state and my responsibility was to ensure that licensees provided professional services in the best interest of their patients and in compliance with Texas laws and regulations. The Board thoughtfully and thoroughly explored relevant pharmacy related topics, challenges, and

strategies to further protect the health and welfare of the citizens of Texas. The Board's duties include writing, revising, and enforcement of regulations, investigations, and action on complaints or offenses, as well as exploration of new advancements in pharmacy practice to meet our consumer protection goals. I continued to serve in that capacity through January 2010, including time as the President of the Board.

20. In October 2004, I was recruited by the Administrator of the Centers for Medicare & Medicaid Services (CMS) to serve as one of four Division Directors of the Medicare Drug Benefit Group. I served in that capacity until October 2005. I played a central role in the initial development, writing, and implementation of Program rules and contracting for the Medicare Part D Program, that began providing benefits on January 1, 2006. In my capacity, I oversaw the development of the Medicare Part D Program's polices and regulations for performance measures, utilization management, quality, safety, medication therapy management, complaints, grievances and coverage determinations including exceptions and appeals.

21. While not directly relevant to the issues in this matter, I have also worked for an early electronic prescribing company, ParkStone Medical, and two pharmaceutical developers and manufactures, Novartis and Abbott.

Terms of Engagement

22. I have been retained by Foley Hoag LLP on behalf of PCMA as an expert in connection with this litigation. I have been asked to provide my opinions on the Act's impact on PBM contracting with employers, health plan clients, and network pharmacies.

PCMA is compensating me for my time at a rate of $500 per hour, including time spent drafting this affidavit.

The Prescription Drug Supply Chain

23. The Prescription drug supply chain consists of at least five key players: manufacturers, wholesalers, health plans, PBMs, and pharmacies. These parties engage in a series of transactions in order to permit an individual to purchase their prescription from a pharmacy while using their pharmacy benefits.

24. Manufacturers. Manufacturers include both producers of innovator or "brand-name" pharmaceuticals and producers of generic or multi-source pharmaceuticals. In most instances, manufacturers do not sell their products directly to pharmacies. Instead, manufacturers sell the bulk of their products to wholesalers. In some instances, a manufacturer may sell directly to pharmacies and the wholesaler only acts as a distributor for the product.

25. For some highly potent drugs or drugs that require significant data collection and patient interaction, manufacturers will limit the distribution of the drug to a limited number of specialty pharmacies. By limiting distribution to specialty pharmacies, manufacturers are better able to track data on the pharmaceutical's usage, which is then reported to the FDA. Sometimes these limitations relate to small patient populations such as orphan or ultra-orphan status products, so the developer may limit access for distribution to no more than a handful of specialty pharmacies across the entire country.

26. Wholesalers. Wholesalers, such as McKesson, AmerisourceBergen, and Cardinal, purchase drugs from manufacturers and sell and distribute the drugs to pharmacies, including both retail and mail order pharmacies. Pharmacies will negotiate drug prices with a wholesaler. The price a pharmacy pays for a drug may vary based on the quantity of the drug the pharmacy purchases and the ability of the pharmacy to negotiate price concessions from the wholesaler.

27. Pharmacies. Pharmacies, including independent pharmacies, chain retail pharmacies, and mail order pharmacies, dispense prescriptions to customers. When an individual presents a valid prescription to a pharmacist, the pharmacists will enter the prescription information and individual's insurance information into an electronic claims processing system that instantly communicates with the health insurer's PBM through sophisticated electronic switching systems. When all outstanding information details have been received from the PBM and confirmed by the pharmacist, the pharmacist will then dispense the filled prescription to the plan member, charge the member their appropriate, contractually required cost-sharing amount, and follow appropriate rules relating to counseling. The claim is submitted to the PBM for the remainder of the negotiated reimbursement amount during the computer submission for filling the prescription.

28. Pharmacies are not obligated to join a PBM's pharmacy network, but they choose to do so because of the financial benefits from increasing their volume of

business. Pharmacies will often agree to pay PBMs service fees to cover costs the PBM incurs administering its pharmacy network.

29. In addition to dispensing prescriptions, network pharmacies will also contract with PBMs to provide vaccinations to health plan members. Some network pharmacies will also be paid to participate in programs such as medication therapy management, drug synchronization, and drug adherence.

30. Many independent pharmacies join Pharmacy Service Administration Organizations ("PSAOs"). PSAOs offer independent pharmacies a variety of services that might help them compete against chain pharmacies and larger independent operations. For example, in some cases, PSAOs offer to contract and negotiate reimbursement terms with PBMs on behalf of their independent pharmacies. PSAOs might also arrange for direct sales between manufactures and independent pharmacies. In rural areas where there may be only one pharmacy, an independent pharmacy can obtain very competitive prices in exchange for participation in a PBM's pharmacy network because the PBM will need to include the pharmacy in its network in order to satisfy the access needs of its customers.

31. PBMs. PBMs play a vital role in managing prescription drug benefits. Nearly every public and private health plan contracts with a PBM to manage some or all of the plan's prescription drug benefits. In fact, approximately 270 million Americans with health coverage through the multitude of commercial, private, and public payer models have their pharmacy/prescription drug plan administered by a PBM. Several

PBMs are payer owned. As explained further below, PBMs offer their health plan customers a variety of services to allow plan members convenient access to pharmaceuticals and helping plan members adhere to their treatment regimen to obtain better health outcomes. PBMs contract with pharmacies to create pharmacy networks, where a plan member can purchase prescription drugs as defined by the coverage terms of the plan. At the same time, at the plan's direction, PBMs will negotiate rebates with pharmaceutical manufacturers. Rebates can be used to reduce the monthly premium amount, to reduce the cost of prescription drugs to the plan and plan members, or to compensate PBMs for their services.

32. Health Plans. PBM customers include employers with self-funded and fully insured employee benefit plans governed by ERISA, health insurers, Medicare Part D plans, state Medicaid plans, and other public and private payers. Health plans contract with PBMs because PBMs offer efficiencies and economies of scale that would be difficult for a plan to achieve on their own. Nearly everyone with a prescription drug benefit is served by a PBM.

PBM-Customer Contracts

33. The PBM industry is very competitive. Health plans will contract with a PBM based on competitive bidding process. Many health plans engage consultants to conduct their contracting negotiations for them. The health plan will inform the consultant of its objectives and priorities in obtaining a prescription drug benefit. In most

cases, the plan will have a list of capabilities and services that they desire from their PBM.

34. Pharmacy networks and pricing are central to the negotiations between plans and PBMs. Plans will dictate the scope of the pharmacy networks they want available to their beneficiaries. While all health plans look to obtain the lowest possible price, some plans are willing to pay more in exchange for more robust service arrangements. In comparison, some plans would prefer to offer more restrictive service provisions and a limited number of pharmacies in exchange for lower prices.

35. Most PBM-Customer contracts are multi-state. Even if the health plan or employer only operates in a single state, their members may live in different states, live on the border of another state, or may need to use their pharmacy benefits while traveling to a different state. In these instances, the beneficiary needs their pharmacy benefits to be able to access their pharmacy benefits across state lines. Therefore, PBMs will contract to create national pharmacy networks on behalf of their health plan clients. This ensures that a plan member will have the same access to their prescription drug benefits regardless of where they live or fill their prescription.

36. PBM-Customer contracts include audit requirements, so the health plan can maintain oversight over how the PBM manages the plan's pharmacy benefits. Health plans mandate and enforce regular audits of the PBM's performance against contractual terms. Typically, a health plan will have audit provisions that specify how, when, for what purpose, for what length of time, and by whom the audits can be conducted. Rebate

audits will almost always be performed by an outside, independent firm. There will also be an audit on administration fees and other direct and indirect remuneration (DIR) that has to be reported to CMS. The audit requirements between a PBM and a health plan will also often allow for separate audits of a plan's discrete lines of business.

PBMs Provide Their Customers With Low Prices and Access

37. PBMs use a number of tools to help their health plan customers balance low prices and improved access to pharmacy benefits, while maintaining the high level of customer satisfaction that health plans expect, including: (1) pharmacy network and contracting strategies, including preferred pharmacy networks, that improve member access to affordable prescriptions and appropriate counseling; (2) access to safe, efficient, and cost-effective mail order prescriptions; (3) access to an accredited specialty pharmacy that provides timely and aggressive patient support and education necessary for achieving quality outcomes for individuals with chronic, complex, or rare conditions; (4) cost effective, clinically sound benefit design and formulary management; (5) enrollment and billing operation; (6) significant patient support such as medication adherence, disease management, utilization management, care coordination, and claims functionality; and (7) rebate negotiations, tracking, and collections. I will go into more detail on some of these tools below.

38. Pharmacy Networks. PBMs create pharmacy networks, where a plan's members can purchase pharmaceuticals using their pharmacy benefits. Pharmacy networks typically include both retail and mail order pharmacies. PBMs negotiate

contracts with network pharmacies, which set the terms for participation in the PBMs pharmacy network. All PBM-Pharmacy contracts require network pharmacies to fill prescriptions consistent with the terms of the member's health plan. PBMs and network pharmacies will also negotiate how much the pharmacy will be reimbursed for claims under the plan, typically through an agreed to reimbursement methodology that reflects changes in drug prices. PBMs and network pharmacies will also agree to various safety and service terms. For Medicare Part D plans, PBMs ensure that a Part D plan's pharmacy network meets CMS's requirements for beneficiaries to have convenient geographic access to a retail pharmacy in their area.

39. The size and structure of a pharmacy network is driven by the specific needs of the health plan. Most plans prioritize the specific needs of their members. When a health plan customer needs access to a wider-network of pharmacies, the PBM will offer pharmacies more favorable terms in order to ensure the pharmacies participate in their network. The PBM will not be able to keep that customer's business if their network does not meet the particular needs of the plan.

40. In order to provide plans with pharmacy networks that meet their particular needs, PBMs frequently will offer plans the choice between single-tier and multi-tier networks. A single-tier network will include a large number of pharmacies, and beneficiaries are able to access their prescription drug benefits at the same prices and cost-sharing obligations regardless of which network pharmacy they choose. Single-tier networks offer plans increased access to pharmacies. In a multi-tier pharmacy network,

there is typically a more limited preferred network of pharmacies and a larger standard network of pharmacies.

41. Preferred Pharmacy Networks offer substantial cost-savings to health plans and their members. Preferred networks include fewer pharmacies, but those pharmacies accept lower reimbursements from plans. Plan members pay lower cost-sharing amounts when they fill a prescription at a preferred pharmacy.

42. Preferred Pharmacy Networks also provide benefits for pharmacies. In exchange for accepting lower reimbursement amounts, preferred pharmacies can expect that the lower cost-sharing obligations for plan members will result in higher store traffic leading to higher sales-volume. PBMs also help boost sales volume at preferred pharmacies in other ways, including promotional materials.

43. Multi-tiered pharmacy networks may also include incentives for beneficiaries to fill certain prescriptions, such as regular maintenance medications, through mail order pharmacies based upon the plan's chosen requirements.

44. Mail order pharmacies provide another lower-cost option for plans that are looking to reduce their members' prescription drug costs. Mail order pharmacies increase access to prescription drugs, in particular for individuals who are immobile or have limited or no transportation options. By making it easier for people to access their prescriptions, mail order pharmacies also help with patient adherence. For many plan members, mail order pharmacies are the preferred way to fill a prescription.

45. PBMs also create specialty pharmacy networks. Specialty pharmacy networks are a key tool that PBMs use to improve the quality of care plan members receive. Specialty pharmacies have expertise in handling drugs that have special storage requirements and providing disease management programs for patients with complex, chronic, or rare diseases. Specialty pharmacies provide medication adherence tracking, patient follow-up, patient education programs, and financial assistance programs. Specialty pharmacies can help improve health outcomes for plan members with the most acute health needs. Because specialty pharmacies focus on complex, chronic, and rare diseases, they are able to purchase larger quantities of pharmaceuticals that treat these conditions, ensuring better availability than a traditional pharmacy, where the store owner will have to consider the potential loss of investment when infrequently prescribed medications expire. As such, specialty pharmacy networks can also create cost-savings. Specialty pharmacies are frequently mail order pharmacies.

46. Claims Processing. PBMs process claims according to the terms of plan. When an individual covered by prescription drug benefits presents a valid prescription, the pharmacist will connect via an electronic claims processing system to the appropriate health insurer identified by the BIN (bank identification number) located on the prescription coverage card (this card could be pharmacy only or may also cover the health benefits). The pharmacy system instantly communicates with the health insurer's PBM through sophisticated electronic switching systems. The PBM will then communicate to the pharmacy the negotiated reimbursement amount for the drug, the

cost-sharing obligation owed by the plan member, coverage limitations information, remaining refills available, refill-too-soon alerts, patient safety and warning messages, such as conflicts of therapy, duplication of therapy, age and gender limitations, and other information related to patient safety and drug adherence. The PBM will also process payment of the claim to the pharmacy for the negotiated reimbursement amount.

47. PBM-Pharmacy contracts typically provide that the pharmacy will be paid according to proprietary formulas created by PBMs to incentivize pharmacies to purchase drugs efficiently and reduce the costs for plans and plan members.

48. PBMs may also pass through fees to network pharmacies to cover the electronic transaction costs related to adjudicating a claim. These electronic transactions include the transmission of electronic prescription information, verification of a patient's insurance coverage, copay or cost-sharing, information on early-refills, duplicate fills, or hard-stops for risks, and other pharmacy benefit related information from the payer. The PBM incurs a fee from these transactions, even if the inquiry is made by the pharmacy. To offset a reasonable portion of those costs, some PBMs add administrative fees to pharmacy transactions.

49. In some instances, a PBM may adjudicate a claim only to later learn that the payment to the pharmacy exceeded the terms of the plan. For example, a pharmacist may unintentionally make an error in entering the claim into the claims processing system that results in the PBM processing the claim at a higher reimbursement than is permitted under the plan. Some PBMs also include performance incentives for

pharmacies, where the reimbursement a pharmacy receives is decreased if it fails to meet certain patient adherence goals for individuals with chronic conditions.

50. Quality of Care Initiatives. PBMs also implement a number of quality of care initiatives on behalf of their client health plans. These initiatives include patient education efforts, drug adherence programs, and disease management. Some PBMs incentivize pharmacies to meet medication adherence goals for conditions such as hypertension, diabetes, and high cholesterol.

51. PBMs also play an active role in managing the quality of the pharmacies in their pharmacy networks. PBMs will review whether the pharmacies in their network meet health, safety, and financial standards. PBMs further serve their health plan customers by validating network pharmacies' current and required state licensure, checking certifications, tracking complaints, and responding to infractions of contractual terms.

52. Cost-Effective Benefit Design. One way that PBMs obtain value for customers is by incentivizing the use of generic drugs instead of more expensive brand-name medications. PBMs offer their clients formularies and cost-sharing requirements to encourage plan members to select less-expensive, but pharmaceutically equivalent, generic drugs.

53. The price a health plan pays for a prescription drug can have a direct impact on the out-of-pocket expenses paid by the health plan member. Many health plans have a co-insurance requirement, by which a member has to pay a set percentage of the price of

the drug paid by the plan. Lower prescription drug costs for the health plan will also result in lower premiums for the plan member. Lower prescription drug costs also reduce the costs for the ultimate payer, the federal government in the case of a Medicare Part D plan and the employer in the case of an ERISA plan.

The Patients Right to Pharmacy Choice Act Harms Plans, Beneficiaries, and PBMs.

54. I have reviewed the Patients Right to Pharmacy Choice Act (the Act) and the description of the Act in PCMA's Memorandum in Support of its Motion for Preliminary Injunction. This description of the Act is attached to this affidavit as Attachment 2. I have also conferred with counsel for PCMA about the meaning of the Act. PCMA's reading of the Act accords with my own understanding of its provisions. Based on this review, and my experience reviewing and implementing statutes and regulations that govern pharmacies, health plans, and the dispensing of drugs, I have concluded that the Act will cause immediate harm to PBMs, health plans, plan members, and the ultimate payer (an employer in the case of ERISA plans and the federal government in the case of Medicare Part D). The Act harms PBMs in two principal ways. First, the Act will require PBMs to fundamentally restructure their business models. Second, the Act will cause PBMs to incur significant administrative costs. I will discuss the specifics of these harms further below.

55. The Network Restrictions. My understanding is that the Retail-Only Pharmacy Access Standards requires PBMs to include pharmacies in their preferred networks that meet certain geographic standards. I understand that the Any Willing

Provider Provision requires a PBM to include any pharmacy in its preferred pharmacy network if the pharmacy is willing to accept the network terms and conditions, and the Beneficiary Direction Provisions prevent PBMs from directing beneficiaries to certain pharmacies. These restrictions undermine the use of preferred pharmacy networks by preventing PBMs from limiting preferred networks to a limited number of pharmacies. Preferred pharmacy networks are an effective means of reducing the price paid for a prescription medication by plans and plan members. Preferred pharmacy networks provide plans a sufficiently large network of pharmacies for the majority of plan members to receive benefits, while using the opportunity for increased claims volume to drive additional savings for the plan and plan members. In rare cases where non-preferred pharmacies are needed to insure access, plans contract with additional locations in their standard network alignment. Absent the ability to limit preferred networks to a limited number of pharmacies or to otherwise direct or incentivize beneficiaries to a limited number of pharmacies, pharmacies will have little incentive to agree to lower drug reimbursements. PBMs will also have to agree to reimbursements that are more generous to pharmacies to attract enough pharmacies into their preferred network in order for the PBM to meet the Retail-Only Pharmacy Access Standards. As a result, the prices that PBMs pay in the first instance will increase. It is highly likely that the prices that plans and plan members pay, including premiums and co-insurance, will also increase.

56. In addition to reducing savings for plans and plan members, the Network Restrictions will result in a substantial administrative burden for PBMs. The Network

Restrictions will require PBMs to re-contract with their existing preferred pharmacies, who are no longer guaranteed access in a limited network. The PBM will also have to contract with new pharmacies that want to be included in a previously limited network. This contracting process requires a significant amount of financial resources and time, likely taking several months or a year. The weakened pharmacy networks could potentially require PBMs to renegotiate pricing guarantees and other contractual terms between PBMs and their health plan clients.

57. The Network Restrictions will also limit the ability of a PBM to offer nationally uniform plan design. Health plans that have preferred pharmacy networks in the other 49 states will not be able to access the benefits of those preferred networks in Oklahoma. Thus, PBMs will have to design and contract pharmacy networks for nationwide plans that provide different benefits in Oklahoma than they do in the rest of the country, which could result in higher out-of-pocket costs for Oklahoma residents in some cases.

58. The Network Restrictions, including the Retail Only Network Access Standard and the Beneficiary Direction Prohibitions, will limit the services that a PBM is able to offer their customer health plans, by making it more difficult for PBMs to offer plans with competitive pricing at mail order pharmacies. Many plan and plan members prefer the use of mail order pharmacies for the cost-savings and convenience that they offer. The Network Restrictions will limit the ability of a PBM to offer that choice. The

Network Restrictions will also make it more difficult for PBMs to provide information to Oklahomans about the mail order pharmacies in their network.

59. Claims Processing Restrictions. I understand that the Affiliated Pharmacy Price Match requires a PBM to pay a pharmacy no less than it pays an affiliated pharmacy for the same drug on a unit-by-unit basis, and the Post-Sale Price Reduction Prohibition prevents PBMs from reducing a previously covered claim, except in cases of fraud or an audit. Together, these restrictions will prevent a PBM from managing a plan's pharmacy benefits according to the plan's terms. For the Affiliated Pharmacy Match Requirement, instead of reimbursing a pharmacy based on the terms negotiated by the PBM with the pharmacy, the PBM will have to check the price on a unit-by-unit basis with all affiliated pharmacies to ensure compliance with the Act. The Post-Sale Price Reduction Prohibition will force health plans to overpay for claims because of an unintentional error or when the contract permits a downward adjustment due to a pharmacy's failure to meet a quality standard instead of recouping overpayments so that pharmacies are paid at their contractually agreed to rates. As a result, PBMs will not be able to deliver the same discounts and cost-savings to customer health plans.

60. My understanding is that Service Fee Prohibition prohibits PBMs from charging pharmacies a fee related to the adjudication of a claim. As described above, PBMs are assessed fees when a pharmacist submits a prescription claim electronically for a plan member served by the PBM. The Service Fee Prohibition will prevent the PBM from passing through these fees to the pharmacy. Because PBMs will be unable to offset

all or a portion of these costs, it will be more difficult for the PBM to meet price and service guarantees in its contracts with customer health plans.

61. For multi-state plans, the Claims Processing Restrictions add another layer of administrative complexity. The PBM will no longer be able to reimburse prescriptions according to the same terms regardless of where the prescription is filled. The PBM will have to create separate processes to ensure that claims in Oklahoma are not paid under their contractually agreed to rate, but at the rate provided to affiliated pharmacies or as originally paid at the point-of-sale, and that any administrative fees incurred for prescriptions filled in Oklahoma are not passed through to the pharmacy as they would be in other states.

62. Network Integrity and Quality Provisions. My understanding is that the Specialty Drug Rule applies the provisions of the Act, including the Retail-Only Pharmacy Access Standards and the Beneficiary Direction Provisions, to specialty drugs. The Specialty Drug Rule will prevent PBMs from being able to create limited networks for specialty pharmacies because there are not enough specialty pharmacies to meet the Retail-Only Pharmacy Access Standards. PBMs will also not be able to direct patients who need specialty drugs to specialty pharmacies. As a result, PBMs will not be able to guarantee that patients receive the disease specific management that specialty pharmacies provide for people with complex, chronic, rare or ultra-rare diseases. Because specialty pharmacies, which were designed to handle medicines that require complex storage and administration, focus on treating people with these conditions, they are able to provide

expanded services that help patients manage their disease and achieve better health outcomes. By design, specialty pharmacies are able to purchase larger quantities of these pharmaceuticals insuring availability that might not be the case at a traditional pharmacy where the store owner has to balance inventory costs and potential loss of investments when limited use causes medication to expire. For this reason, specialty pharmacies not only provide targeted care, but they are able to dispense frequently expensive medications with more services and less time constraints.[1] PBMs will no longer be able to provide these benefits to health plans and members in Oklahoma.

63. The Pharmacy Termination Prohibition also restricts a PBMs ability to guarantee that all network pharmacies provide the quality of care members expect. I understand that this provision prevents a PBM from removing a pharmacy from its network because the pharmacy employs a pharmacist whose license is suspended. While not all pharmacies who employ a suspended pharmacist need to be removed from a network, there are instances where the suspension reflects on the pharmacy's ability to provide pharmaceutical services. There are instances where keeping a pharmacist in the network could put the plan or the members at risk. For example, there could be evidence

[1] Due to the extreme potency and potential serious safety concerns of some of these specialty pharmaceuticals, the FDA has required select products to be in a Risk Evaluation and Mitigation Strategy (REMS) program. For this and other reasons, some manufacturers will have an extremely limited distribution network that may only include one or a limited few specialty pharmacies. Specialty pharmacies provide intense data collection and monitoring for these programs.

of fraud or other misconduct but did not meet the evidentiary standard needed for a Board of Pharmacy to remove the license.

64. Health Insurer Monitoring Requirement. I understand the Health Insurer Monitoring Requirement requires health plans to monitor a PBM's activities under the Act, and the Contract Approval requires health plans to approve all contracts between a PBM and its retail pharmacy network. The Health Insurer Monitoring Requirement and the Contract Approval Rule place a significant administrative burden on plans. PBM-Customer contracts already include audit requirements to ensure that PBMs are acting in accordance with the terms of the plan and in compliance with state and federal law. Health plans lack the expertise to review a PBM's network contracts. Health plans contract with PBMs because they do not have the expertise to conduct this type of pharmacy network review.

The Harm Will Be Particularly Acute During COVID-19

65. PBMs have been aggressive in their response to the COVID-19 pandemic. PBMs have worked with their health plan clients to ensure that plan members are able to access their prescription drug benefits while maintaining social distancing. I am aware of PBMs implementing several changes in policies to maintain safe access to pharmaceuticals including: waiving signature requirements, permitting early refills for certain medications, and monitoring prescription drug supply chains to prevent drug shortages.

66. At the same time that PBMs are taking affirmative steps to ensure plan members are able to access their prescription drug benefits, federal and state governments have been adopting many emergency policy changes to address the COVID-19 pandemic. Generally, PBMs have a single team dedicated to monitoring changes in federal and state statutes and regulations. This team will then coordinate with various operational teams, who implement any changes required in the PBM's customer contracts, pharmacy contracts, and clinical and reimbursement practices that are now required by federal or state law. Many of the federal and state regulatory changes related to COVID-19 will require PBMs to re-negotiate agreements with health plans and pharmacies and to engage with pharmacies to implement new health and safety measures. PBMs also have to communicate these federal and state policy changes to plan members.

67. Implementing the Act during the COVID-19 pandemic will create particular challenges for PBMs and their health plan customers. In my experience, the operational teams that are needed to implement the changes required in the Act will be the same teams that are implementing various federal and state emergency orders and actively ensuring that plan members have uninterrupted access to pharmacy benefits. PBMs will have to spend significant resources re-negotiating pharmacy network agreements and ensuring compliance with the Act at the same time they are engaging with network pharmacies to address acute challenges related to COVID-19. Similarly, PBMs will have to revise all communications to members in Oklahoma to ensure promotional materials meet the requirement of the Act, when their attention is focused on

providing important health and safety information to members related to the COVID-19 pandemic. Therefore, the very individuals who are presently responsible for the PBM's response to COVID-19 will have the added responsibility of leading the PBM's efforts to comply with the Act.

Reservation

68. I reserve my rights to amend, modify, supplement and/or further support my opinions based on, inter alia, information learned during discovery, including without limitation obtained from documents and/or testimony that are produced or otherwise obtained after the preparation of this affidavit. I further reserve my rights to rebut any expert opinion proffered by the defendant in this action.

I declare under penalty of perjury that the foregoing is true and correct. Executed May 13, 2020.

/s/ Kim. A. Caldwell

Kim A. Caldwell

Attachment 1

Kim A. Caldwell, RPh

3329 Drip Rock Drive, McKinney, TX 75070 | (214) 392-1096 | texascaldwell@yahoo.com

Skills, Experiences, and Abilities

Pharmacy – more than 40 years practicing pharmacy in all areas except nuclear pharmacy; previous owner operator of an independent pharmacy, chain pharmacy pharmacist/manager/operations; long-term care consultant; health system pharmacist; geriatric care pharmacy services; chapter author in pharmacy textbook, Managed Care Pharmacy Practice (2nd edition) Navarro

Policy, Legislative, Regulatory – CMS Division Director helped lead creation of program rules for Medicare Part D; Texas State Board of Pharmacy member over 12 years of service including time as Board President; dozens of face-to-face meetings with members and staff at White House, US Senate, US House, HHS, OIG, CMS, CMMI, FDA, CDC, and numerous state officials elected and staff

Population management, Population health – created and operated dedicated research business; Active participant in MIT NEWDIGS' FoCUS and LEAP projects, Previous Brooking Institute and Duke-Margolis participant; previous guest speaker for National Health Policy Forum; regular speaker for national health conferences (for example: 2019: Paying for Cures Conference – Washington, DC; National Health Council Leadership Conference – Fort Lauderdale, FL; AMCP Spring Conference – San Diego, CA; AMCP Nexus Conference – Washington, DC); commentator for FDA-FTC public workshop on biosimilars

Leadership – proven leader of people, programs, processes, strategy, and outcomes; repeatedly honored by others for leadership; recognized mentor of talent both up and down the organization chart

Awards

NEXT GENERATION LIFETIME LEADERSHIP OF THE YEAR AWARD - 2018

- Parata / Pharmacy Times

STEPHEN G. AVEY AWARD - 2018

- Academy of Managed Care Pharmacy Foundation

NABP HONORARY PRESIDENT - 2011

- National Association of Boards of Pharmacy

DISTINGUISHED SERVICE AWARD - 2010

- Academy of Managed Care Pharmacy

Experience

PRINCIPAL | TEXAS STAR HEALTHCARE CONSULTING, LLC | APRIL 2018-PRESENT

- With more than four decades of experience within the complex and often disparate world of pharmaceutical health benefits and coverage, refocused priorities toward assisting others through independent consulting services. Primary areas of service target Medicare Part D; Pharmacy policy, operations, reimbursement; PBMs; US Healthcare pharmacy/pharmaceutical benefits and coverage. Recent clients include drug developers, payers, PBMs, home infusion pharmacies, trade/professional organizations, investor groups, education providers, and think tanks.

Kim A. Caldwell, RPh

MARKET VICE PRESIDENT | HUMANA, INC. | APRIL 2008-JULY 2018

- Leader of two distinct teams: (1) Pharmacy Professional Affairs – a small group of subject matter experts who focus their expertise and influence on pharmacy related policy and regulatory issues, and (2) Comprehensive Health Insights, Inc. – an evidence based research organization that target population health research questions on behalf of internal Humana, Public/Private research such as those linked to the FDA Sentinel, PCORI, and select universities, Pragmatic Trials, and Collaboration partnerships. Advised on key components such as P&T, benefit design, networks, and Part D bids.

SR. DIRECTOR, CORPORATE GOVERNMENT AFFAIRS AND REIMBURSEMENT | ABBOTT LABS | OCTOBER 2005-APRIL 2008

- Worked across Abbott corporately, across the industry, and with key staff throughout CMS and on Capitol Hill specifically targeting product coverage, reimbursement, financing, and related issues.

DIVISION DIRECTOR, MEDICARE DRUG BENEFIT GROUP | CENTER FOR MEDICARE AND MEDICAID SERVICES (CMS) | OCTOBER 2004-OCTOBER 2005

- Recruited to be the leader of the Division of Clinical and Economic Performance in the Center for Beneficiary Choices (CBC), one of four divisions charged with the creation of Part D.
- Helped hire staff while helping to lead the development, implementation, and initial contracting of Medicare Part D – the Medicare prescription drug benefit that began January 1, 2006.
- Among other duties, this division was responsible for the first level oversight for much of the drug benefit including performance measures, utilization management and measures, quality, safety, medication therapy management, complaints, grievances, and coverage determinations including exceptions and appeals.

ASSOCIATE DIRECTOR, CORPORATE ACCOUNTS | NOVARTIS PHARMACEUTICALS | OCTOBER 2001-OCTOBER 2004

- Leader of full client engagement for two national customer organizations
- Participated as active member of key new product advisory teams

PRIVACY OFFICER / VICE PRESIDENT - PHARMACY | PARKSTONE MEDICAL | 2000-2001

- Leader of the interface between product development (early stage electronic prescribing) and pertinent federal and state laws, rules, and regulations
- Led the clinical pharmacy team

VICE PRESIDENT, PHARMACY REGULATIONS; VICE PRESIDENT, CLINICAL OPERATIONS | ADVANCEPCS | 1998-2000

- Led various teams/projects enhancing the clinical offerings and delivery of services.
- Led the restructuring of key mail order pharmacy quality controls and operational strategies.
- Managed and grew clinical support team functions and productivity.
- Served on the PBMs P&T Committee and formulary development teams.

Kim A. Caldwell, RPh

PHARMACY DIRECTOR; CLINICAL PHARMACIST | NYLCARE HEALTHPLANS_AETNA_PRUDENTIAL HEALTH PLAN_AETNA | 1996-1998

- This brief period of time saw my company being purchased by Aetna – I chose to move to a third company which was also purchased by Aetna.
- Managed numerous clinical, financial, and benefit design and implementation functions including leading P&T Committees, building formularies, and negotiation product contract terms.
- Utilizing data analytics, was critical managed payer risk arrangement partnerships and network pharmacy contracting and performance relationships.

RETAIL PHARMACY DIRECTOR | BAYLOR-RICHARDSON MEDICAL CENTER | 1994-1996

- Established, opened, and operated a retail pharmacy within a medical office building attached to the parent hospital.
- Began pharmacy consultations with the hospital's oncology center.
- Established an onsite consultant pharmacist position within the parent hospital's standalone senior clinic.

PHARMACIST, CLINICAL PHARMACIST, CONSULTANT, OWNER | VARIOUS RETAIL (INDEPENDENT AND CHAIN) PHARMACIES PLUS MULTIPLE RURAL NURSING HOMES | 1975-1994

- Following graduation, externship, internship, and full licensure, I had the opportunity to work with and learn from a great group of pharmacy leaders.
- Highlighted among the others was the opportunity to be the owner/operator of a small independent pharmacy in East Texas from 1979-1985.
- As the times dictated, I also served as pharmacy consultant for various small, regionally located nursing facilities on weekends and days off.

Education

BS PHARMACY | JULY 1974 | SOUTHWESTERN OKLAHOMA STATE UNIVERSITY

- Major: Pharmacy
- Minor: Biology/Chemistry

Attachment 2

Summary of the Act

1. The Act's "Network Restrictions"

- Each standard and preferred pharmacy network must be designed so that a certain percentage of network beneficiaries lives within a set geographical distance from at least one network pharmacy. *Retail pharmacies*, but not mail-order pharmacies, count toward these *access standards*. 36 O.S. § 6961(A)-(B) (the "Retail-Only Pharmacy Access Standards").
- PBMs must allow *any willing pharmacy* to participate in the PBM's preferred network if that pharmacy agrees to that network's terms and conditions. 36 O.S. § 6962(B)(4) (the "Any Willing Provider Provision").
- PBMs may not *deny, limit or terminate pharmacy* contracts because a pharmacist employed by the pharmacy is on probation with the State Board of Pharmacy. 36 O.S. § 6962(B)(5) (the "Probation-Based Pharmacy Limitation Prohibition").
- The three "Beneficiary Direction Provisions," restrict PBMs from directing beneficiaries to certain pharmacies:
    - PBMs may not require beneficiaries to use pharmacies directly or indirectly owned by the PBM (*i.e.*, an *affiliated pharmacy*). 36 O.S. § 6961(C) ("Affiliated Pharmacy Requirement Prohibition").
    - If a PBM lists one pharmacy on *promotional materials*, then it must list all pharmacies "participating in the preferred and nonpreferred pharmacy and health networks." 36 O.S. § 6961(D) (the "Promotional Materials Provision").

Summary of the Act

- PBMs may not give *beneficiaries incentives*, such as discounts, to buy drugs at particular pharmacies. 36 O.S. § 6963(E) (the "Beneficiary Incentive Prohibition").

2. The Act's "Claims Processing Provisions"

- PBMs may not charge pharmacies *service fees* relating to the adjudication of a claim. 36 O.S. § 6962(B)(2) (the "Service Fee Prohibition").
- The reimbursements PBMs pay to un-affiliated pharmacies must *match* those it pays to *affiliated pharmacies* on a unit-to-unit basis. 36 O.S. § 6962(B)(3) (the "Affiliated Pharmacy Price Match").
- PBMs may not, *post-sale*, *reduce the price* paid to a pharmacy for a covered claim, or deny reimbursement, except in cases of fraud, or errors uncovered in an audit. 36 O.S. § 6962(B)(6) (the "Post-Sale Price Reduction Prohibition").
- PBMs must *pay terminated network pharmacies* outstanding claims upon termination. 36 O.S. § 6962(B)(7) (the "Termination Payment Requirement").

3. The Act's "Health Insurer Obligations"

- *Health insurers must monitor* all activities carried out by, or on behalf of, the health insurer under the Act, and those with whom the health insurer contracts. 36 O.S. § 6963(A)-(B) (the "Health Insurer Monitoring Requirement").

4. The Regulations

- Health insurers must *approve all contracts* used by its contracted PBMs and retail pharmacy networks to ensure compliance with the Act. Okla. Admin. Code § 365:25-29-9(c)(1) (the "Contract Approval Rule").

Summary of the Act

- The Act applies to *specialty drugs*. Okla. Admin. Code § 365:25-29-7.1(a)(2) (the "Specialty Drug Rule").
- The "Promotional Materials Rule": If PBMs list one pharmacy on its *promotional material*, then it must list all pharmacies on that material. Okla. Admin. Code § 365:25-29-7.1(a)(3) (the "Promotional Materials Rule").